## **REMARKS**

Claims 1, 2, 4, 14, 15, and 18 are pending for consideration. Claims 1 and 18 are currently amended. Claims 3, 5-13, 16-17, and 19-52 are canceled without prejudice.

Claim 1 has been amended to:

- spell out "immune response modifier" as required by the Examiner.
- specify that the IRM and polymer are "covalently" attached (incorporated from canceled claim 6).

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- list specific IRM compound classes (incorporated from canceled claim 27).
- list specific polymer classes (incorporated from canceled claim 32).

Claim 18 has been amended to spell out "toll-like receptor" as required by the Examiner. No new matter has been added.

# Claim Objections

It is submitted that the objections to claims 1 and 18 have been overcome as required by the Examiner.

#### Claim Rejections – 35 USC 112

Claims 1-2, 4, 6 and 14-15 were rejected under 35 USC 112, first paragraph, for failing to comply with the written description requirement.

Claim 1 has been limited to specific IRM compound classes and it is therefore submitted that the rejection has been overcome.

## Claim Rejections – 35 USC 102

Claims 1, 4, 6, 14-15 and 27 were rejected under 35 USC 102(b) as being anticipated by Hedenstrom et al. (US 2003/0045543).

Claim 1 requires that the polymer and IRM compound are covalently linked. The formulations of Hendenstrom et al. are mixtures. There is no disclosure or suggestion to run a chemical reaction to <u>covalently</u> attach the IRM compound to a polymer, nor is there any reason

to believe such reaction would occur spontaneously. Therefore, it is submitted that the claims are not anticipated and the rejection should be withdrawn.

Claims 1, 4, 6, 17, 28, and 32 were rejected under 35 USC 102(b) as being anticipated by Paal et al. (US 5,212,186).

Claim 1 has been amended to list particular IRM compound classes which do not include benzimidizoles. Therefore, it is submitted that the claims are not anticipated and the rejection should be withdrawn.

Claims 1, 4, 6, 14-15, 17-18, 27 and 32 were rejected as anticipated by Krieg et al. (US 2003/0139364).

Krieg does not disclose IRM compounds covalently linked to a polymer. The polymers referred to are "carriers," which does not suggest any direct covalent attachment but rather a conventional formulation mixture. The cross-linking referred to in Krieg is clearly conventional cross-linking of polymers, not any covalent linkage to the IRM compound. There is no implication in Krieg of any cross-linking to the IRM compound. The Office Action asserts that it is reasonable that the IRM compounds are covalently attached to the soluble polymer because covalent bonding is the sharing of pair electrons between atoms. However, there is no indication at all in Krieg of any such "sharing of electron pairs" with atoms of the IRM compound, nor is there any reason why one skilled in the art would assume so. Krieg does not suggest a spontaneous chemical reaction would create a covalent bond between the polymer and IRM compound, and one skilled in the art would run a chemical synthesis to do so as shown in the present application.

Therefore, it is submitted that the claims are not anticipated and the rejection should be withdrawn.

## Claim Rejections – 35 USC 103

Claims 1-2, 4, 6, 14-15, 17-18, 27-28 and 32 were rejected under 35 USC 103(a) as being unpatentable over Krieg et al. (US 2003/0139364) in view of Paal et al. (US 5,212,186) and further in view of Hoffman et al. (US 6,165,509).

As discussed above, Krieg et al. does not disclose or suggest <u>covalently</u> linking the IRM compound to a polymer. Paal and Hoffman do not involve compounds of the IRM classes required by amended claim 1. There is no motivation or reasonable expectation of success based on the cited references that IRM compounds and polymers of the claimed invention could by covalently attached and that such combination would be biologically active or useful. Krieg is clear that the matrix referred to is a conventional mixture formulation and the polymer cross-linking referred to is merely conventional cross-linking of the polymer, not polymer-IRM compound cross-linking. Accordingly, it is submitted that the claims would not have been obvious to one of ordinary skill in the art and the rejection should be withdrawn.

#### **Double Patenting**

Claims 1-2, 4, 6, 14-15, 17-18, 27-28 and 32 [-23] were provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 13-14 of US application 12/304,339 as evident by Krieg et al. (US 2003/0139364).

Claims 1-2, 4, 6, 14-15, 17-18, 27-28 and 32 [-23] were provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1, 3, 12 and 14 of US application 10/821,335.

A terminal disclaimer is included herewith in connection with the '335 application.

However, with respect to the 12/304,339 application claims 13-14, Applicant respectfully traverses. The '339 application was filed subsequent to the present application and claims 13-14 require the inclusion of a thermoresponsive gel and are thus patentably distinct over the present application. Applicant respectfully submits that the present application claims should be allowed to issue prior to the '339 application.

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In view of the above, it is submitted that application is in condition for allowance. Favorable action is therefore requested.

Respectfully submitted,

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